

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for inflamed conditions and common skin disorders, including eczema, allergies, nervous itch, and fungus infections; that the action of the article was essentially similar to that of penicillin; and that it represented a new concept in sustained action skin medication; 502(e) (2)—the label failed to bear the common or usual name of each active ingredient since the labeling of the article represented that the ointment base was itself an active ingredient and the label did not disclose the identity of the ointment base or list its ingredients; and 502(f) (2)—the labeling failed to bear such adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users since its labeling failed to bear a warning in essentially the following form: "Warning: Not for prolonged use. Do not apply to large areas of the body. If redness, irritation, or swelling of the skin develops or pain persists or increases, discontinue use and consult a physician. Do not use in the eyes."

DISPOSITION: 5-25-59. Default—destruction.

5906. Electronic devices. (F.D.C. No. 41510. S. Nos. 16-164/5 P, 16-168 P.)

QUANTITY: 2 labeled devices and 1 unlabeled device at Newport, Ky., in possession of J. Vincent Reed, D.C.

SHIPPED: About 1939, 1943, and 1946, by Electronic Instrument Co., from Tiffin, Ohio.

LABEL IN PART: (On device) "Radioclast Model 40 Mfd. by Electronic Instrument Co., Tiffin, Ohio," (name plate) "Radioclast Mfd. by J. G. Miller, Tiffin, Ohio for the Electronic Instrument Co. Distributors Tiffin, Ohio Model 40 Serial 72," and (name plate) "Radioclast Mfd. by Electronic Instrument Company Tiffin, Ohio Model P."

ACCOMPANYING LABELING: Leaflets entitled "Electronic Laboratory Analysis Rates: Numerically Arranged" and "Electronic Analysis," shipped during March 1957, and on 1-14-58, by Electronic Instrument Co., Tiffin, Ohio.

RESULTS OF INVESTIGATION: Examination showed that the *Radioclast Model 40* consisted of a console desk-type instrument. The electronic elements of the instrument included a series of variable resistors, a group of coils, a power supply, an amplifier or oscillator unit, and a bakelite plate indicator. The panel contained 24 control knobs, 2 meters, a timer, and 9 plug-in connections.

The *Radioclast Model P* was similar to the above-described Model 40 but was smaller and was portable. The panel contained 11 control knobs, two switches, electrode connections, and a bakelite plate indicator.

The unlabeled unit was an electronic-magnetic treating unit. The panel contained 6 control knobs, a meter, and 4 electrode connections. Two sets of electrodes were used: (1) The electronic electrodes, which were to furnish a low-voltage, low-frequency current to the body; and (2) the magnetic electrodes which were to set up a magnetic field in the body between the electrodes. The bottom of the unit was a storage drawer.

LIBELED: 4-11-58, E. Dist. Ky.; libel amended 6-6-58.

CHARGE: 502(a)—when shipped and while held for sale, the labeling accompanying the devices contained false and misleading representations that the devices were capable of diagnosing or treating disease conditions of the brain, tonsils, prostate, spinal cord, trachea, lungs, kidneys, stomach, heart, liver, bones, eyes, and numerous other disease conditions; and 502(f) (1)—while held

for sale, the labeling of the devices failed to bear adequate directions for use for the purposes for which they were intended, namely, for diagnosing or treating leg trouble, menopausal difficulties, arthritis, poisons in the body, underactive or overactive organs, and fractures, which were the conditions for which they were orally represented by J. Vincent Reed, D.C., on 2-5-58.

DISPOSITION: On 5-19-58, J. Vincent Reed, D.C., claimant, filed an answer denying that the devices were misbranded as alleged in the libel, and on the same day filed a motion to dismiss the libel. The motion to dismiss was overruled on 6-24-58.

On 11-5-58, the Government filed written interrogatories which were served against the claimant. Subsequently, the Government filed a motion for order of default decree of condemnation for failure to answer the interrogatories. On 12-15-58, the claimant filed a second motion to dismiss the libel. The court, on 12-16-58, denied claimant's motion and denied also the Government's motion for default decree. The Government then filed a motion for order compelling an answer by the claimant to the written interrogatories. The court granted the motion on 12-30-58.

Thereafter, the Government and claimant having stipulated on additional facts, and having submitted the matter to the court for decision, the court, on 5-15-59, handed down findings of fact and conclusions of law to the effect that the leaflets accompanied and served to misbrand the devices. The court made no finding of misbranding under 502(f) (1).

On 5-21-59, judgment of condemnation was entered and the court ordered the devices to be delivered to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

5907. Medicated feed. (F.D.C. No. 42903. S. No. 48-142 P.)

QUANTITY: 18 100-lb. bags at West Bridgewater, Mass.

SHIPPED: 2-13-59, by Dean & Lee, from Horseheads, N.Y.

RESULTS OF INVESTIGATION: The article was shipped in response to an order for a poultry feed containing 0.0125 percent sulfaquinoxaline.

Examination showed that the article delivered contained about 0.095 percent sulfaquinoxaline.

LIBELED: 3-25-59, Dist. Mass.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(b)—the label of the article failed to bear (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e) (2)—the label failed to bear the common or usual name of each active ingredient; 502(f)—the labeling failed to bear (1) adequate directions for use and (2) adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of the user.

DISPOSITION: 5-4-59. Default—destruction.

5908. Hexadin, Arsan Powder, and Weatol. (F.D.C. No. 42927. S. Nos. 22-121/3 P.)

QUANTITY: 6 cases, 12 1-lb. jars each, and 4 25-lb. drums, of *Hexadin*, 10 8-oz. jars of *Arsan Powder*, and 2 1-gal. jars of *Weatol*, at Superior, Nebr.